DePuy Mitek
a Johnson & Johnson company

K130169

MAY 0 1 2013

510(k) SUMMARY

Date Prepared January 22, 2013

Submitter's Name and Address:

DePuy Mitek, Inc.
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325 Paramount Drive
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Contact Person

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Name of Medical Device

Classification Name: Arthroscope: 21 CFR 888.1100

Common: Pump

Trade Name: FMS VUE Fluid Management & Tissue Debridement System
FMS Connect Interface Cable

FDA Classification: II

FDA product code: HRX

Predicate Device(s)

The proposed **FMS VUE Fluid Management & Tissue Debridement System**, and **FMS Connect Interface Cable** are substantially equivalent to:

- K954465 FMS DUO (November 9, 1995)
- K002040 FMS SOLO (September 11, 2000)

Device Description

The FMS VUE is DePuy Mitek's next generation of Fluid Management and Tissue Debridement System. The system consists of a pump, tube sets, and the following optional accessories Foot Pedal, Remote Control, Handpiece and FMS Connect Interface Cable.

As with its predicate devices, FMS DUO+ and FMS SOLO, this system utilizes pump technology designed to provide a range of arthroscopic surgical treatments including soft tissue ablation, contouring, cutting and coagulation and temperature control.

The FMS VUE provides irrigation (inflow) and aspiration (outflow) of fluid to and from joint cavities during arthroscopic procedures by way of 2 peristaltic roller pumps. Both roller pumps are software controlled to automatically manage fluid and intra-articular joint pressure based on default settings or adjusted setting chosen by the surgeon. Additionally, the pumps automatically manage shaver and cannula suction. By controlling both flow and pressure setting, the FMS VUE Fluid Management & Tissue Debridement System accurately regulates pressure and flow in the joint.

The FMS VUE can be used in either the DUO mode (default mode) which provides irrigation, shaver control and suction or the SOLO mode which provides irrigation and shaver control but not suction.

Like its predicates, the FMS VUE also incorporates an integrated debridement function for controlled shaving and burring of tissue and bone.

The **FMS Connect Interface Cable** allows the use of competitive shaver systems to interface with the FMS VUE. When the FMS Connect device is attached to the cable of a competitors hand piece and the hand piece is running, the FMS Connect sends a signal to the FMS VUE.

Indications for Use

DePuy Mitek FMS VUE Fluid Management and Tissue Debridement System is intended to provide controlled fluid distention and suction, controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic surgery of the shoulder, knee, ankle, elbow, wrist and hip joints.

The FMS CONNECT Interface Cables are accessories to the DePuy Mitek FMS Fluid Management and Tissue Debridement Systems; they connect competitive shavers to FMS arthroscopy pumps.

Comparison to Predicate Device

This submission is intended to demonstrate that the FMS VUE and FMS Connect Interface Cable are substantially equivalent to their legally marketed devices: FMS DUO+ (K954465) and FMS SOLO (K002040).

The FMS VUE Fluid Management & Tissue Debridement System and FMS Connect Interface Cable have been carefully compared to legally marketed devices with respect to intended use, essential components and material, performance specifications and technology characteristics. They have the same Indications for Use and technology characteristics.

- Enhancements on the FMS VUE include:
  - Incorporating DUO+ and SOLO mode functionality in one pump system
  - Measurement displayed in mmHg
- FMS Connect Interface Cable has a different mode of connecting to completive shavers and is powered for a wall source rather that the pump.

Safety and Performance

Verification of the FMS VUE Fluid Management & Tissue Debridement System and accessories includes electrical, software and performance tests to show that the device meets its product specifications over a range of operating conditions. Validation testing for the FMS VUE includes testing to show the device meets user needs. Verification testing conform to the following Standards and Guidance documents:

TABLE 1 Standards & Guidance Documents

Standard/ Guidance	Description
EN 60601-1:2005	Medical electrical equipment -- Part 1: General requirements for safety
EN60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
IEC 62304:2006	Medical device software-software life cycle process
Guidance for the Content of Premarket Submission for Software Contained in Medical Devices: 2005	
General Principals of Software Validation; Final Guidance for Industry and FDA Staff: 2002	
Guidance Off-The-Shelf Software Use in Medical Devices: 1999	

Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The FMS VUE Fluid Management & Tissue Debridement System and FMS Connect Interface Cables do not differ from the predicate device in fundamental scientific technology or intended use.

Conclusion

Safety and performance testing have been executed to validate the performance and safety of the devices. It has been demonstrated that these device modifications will not affect safety and effectiveness of the subject devices. Results of performance and safety testing have demonstrated that the modified device is suitable for its intended use.

Based on the indications for use, fundamental scientific technology, and comparison to the predicate devices, the FMS VUE Fluid Management & Tissue Debridement System, and FMS Connect Interface Cable are shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 1, 2013

DePuy Mitek, Inc.
% Ms. Susan Kagan
Project Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K130169
Trade/Device Name: FMS VUE Fluid Management & Tissue Debridement System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: January 22, 2013
Received: February 07, 2013

Dear Ms. Kagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130169

Device Name: FMS VUE™ Fluid Management and Tissue Debridement System

Indications for Use:

DePuy Mitek FMS VUE Fluid Management and Tissue Debridement System is intended to provide controlled fluid distention and suction, controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic surgery of the shoulder, knee, ankle, elbow, wrist and hip joints.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off) For

Division of Surgical Devices

510(k) Number K130169

Indications for Use

510(k) Number (if known): K130169

Device Name: FMS™ Connect Interface Cable

Indications for Use:

The FMS CONNECT Interface Cables are accessories to the DePuy Mitek FMS Fluid Management and Tissue Debridement Systems; they connect competitive shavers to FMS arthroscopy pumps.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S For

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K130169